

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
United States Patent and Trademark
Office
Box PCT
Washington, D.C.20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 06 December 1999 (06.12.99)	
International application No. PCT/EP99/02930	Applicant's or agent's file reference 20388P WO
International filing date (day/month/year) 29 April 1999 (29.04.99)	Priority date (day/month/year) 29 April 1998 (29.04.98)
Applicant BÖHLE, Andreas et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

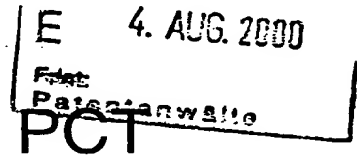
19 November 1999 (19.11.99)

☐ in a notice effecting later election filed with the International Bureau on:
2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No.: (41-22) 740.14.35</p>	<p>Authorized officer C. Cupello</p> <p>Telephone No.: (41-22) 338.83.38</p>
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From the
INTERNATIONAL PRELIMINARY-EXAMINING AUTHORITY



To:

WEICKMANN WEICKMANN HUBER LISKA
PRECHTEL BÖHM WEISS TIESMEYER
HERZOG RUTTENSBERGER
Kopernikusstrasse 9
D-81679 München
ALLEMAGNE

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing
(day/month/year) 02.08.2000

Applicant's or agent's file reference
20388P WO

IMPORTANT NOTIFICATION

International application No.
PCT/EP99/02930

International filing date (day/month/year)
29/04/1999

Priority date (day/month/year)
29/04/1998

Applicant
BÖHLE, Andreas

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/



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Fax: +49 89 2399 - 4465

Authorized officer

Senkel, H

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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference 20388P WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP99/02930	International filing date (<i>day/month/year</i>) 29/04/1999	Priority date (<i>day/month/year</i>) 29/04/1998
International Patent Classification (IPC) or national classification and IPC A61K35/74		
Applicant BÖHLE, Andreas		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 6 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 19/11/1999	Date of completion of this report 02.08.2000
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Markopoulos, E Telephone No. +49 89 2399 8658 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP99/02930

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-15 as originally filed

Claims, No.:

1-25 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 1-15 in respect to industrial applicability.

because:

- ☒ the said international application, or the said claims Nos. 1-15 relate to the following subject matter which does not require an international preliminary examination (*specify*):

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP99/02930

see s parat sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the said claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	10-23
	No:	Claims	1-9, 24, 25
Inventive step (IS)	Yes:	Claims	-
	No:	Claims	1-25
Industrial applicability (IA)	Yes:	Claims	16-25
	No:	Claims	-

2. Citations and explanations

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 1-15 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: BIR M. ET AL: '[Management of exceptional papillomavirus-related diseases by BCG immunostimulation]. TRAITEMENT DES AFFECTIONS EXCEPTIONNELLES A PAPILLOMA VIRUS PAR IMMUNOSTIMULATION AU BCG.' SEMAINE DES HOPITAUX, (1988) 64/22 (1525-1528). , XP002122559

D2: STRAUSS M ET AL: 'Aerodigestive tract papillomatosis: bacille Calmette-Guerin (BCG) immunotherapy.' LARYNGOSCOPE, (1982 SEP) 92 (9 PT 1) 971-5. , XP002122562

D3: MALISON M D ET AL: 'Attempted BCG immunotherapy for condylomata acuminata [letter].' BRITISH JOURNAL OF VENEREAL DISEASES, (1981 APR) 57 (2) 148, 150. , XP002122563

D4: COHEN HA ET AL: 'Topical treatment of Kaposi's sarcoma, basal cell carcinoma and solar keratosis with ointment of BCG and cord factor' DERMATOLOGICA, vol. 158, no. 2, 1979, pages 117-25, XP002122560

D5: GB-A-2 179 858 (BOEHRINGER INGELHEIM INT) 18 March 1987 (1987-03-18)

2. D1 discloses the treatment of papilloma virus related diseases by BCG immunostimulation whereby the genital located condylomatoses show positive results in 76,9% (p. 1527, col. 1, par. 3).

D2 also discloses a BCG immunotherapy, administered to patients with laryngeal and/or

tracheobronchial papillomas by intradermal inoculation. There is the recommendation to use it along with standard endoscopic removal as a successful adjuvant, too (p. 973, col. 2, l. 1 - p. 974, col. 1, l. 53).

Therefore, claims 1-7, 9, 24, and 25 do not fulfill the requirements of Article 33(2) PCT in respect to novelty.

Regarding claim 8 and insofar it can be understood (see item VIII), both D1 and D2 disclose an application once weekly for 4 weeks (at least in the beginning of the treatment, see D2). With each inoculation 3×10^8 organisms were given (D2). It can be assumed that the amount of organisms applied in D2 falls within the range claimed in claim 8, hence claim 8 also cannot be considered as novel.

3. D3 describes an attempted BCG immunotherapy for Condylomata acuminata, D4 an effective topical treatment of Kaposi's Sarcoma by using emulsions or ointments containing killed BCG and cord factor (p. 124, l. 35-39), and D5 the treatment of warts such as Condylomata acuminata by using a composition comprising a keratolytic agent like salicylic acid and a non-specific nucleoside analogue (p. 2, l. 15-27).

The problem to be solved by the present invention may be regarded as finding an alternative BCG composition for the treatment of papilloma virus caused diseases. Since it is known from D4 to use BCG in an ointment for topical application and from D5 to use keratolytic agents in the treatment of warts, no inventive step seems to be present for the remaining claims 11-23.

The subject-matter of claim 10 also is not considered to involve an inventive step because the feature "laser" is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

4. For the assessment of the present claims 1-15 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item VIII**Certain observations on the international application**

1. Claims 7 and 20 do not meet the requirements of Article 6 PCT in that the dependencies to previous claims are incorrect.
2. Regarding claim 8, the matter for which protection is sought is not clearly defined due to the wording of the claim.

A-D

PATENT COOPERATION TREATY

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INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 20388P WO	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/EP 99/ 02930	International filing date (day/month/year) 29/04/1999	(Earliest) Priority Date (day/month/year) 29/04/1998
Applicant BÖHLE, Andreas		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☒ Certain claims were found unsearchable (See Box I).

3. ☐ Unity of invention is lacking (see Box II).

4. With regard to the title,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

TREATMENT OF PAPILLOMA VIRUS INFECTION USING A MYCOBACTERIUM

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☐ Non of the figures.

INTERNATIONAL SEARCH REPORT

International application N .

PCT/EP 99/ 02930

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
Remark: Although claims 1-15 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 99/02930

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61K35/74

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	BIR M. ET AL: "Management of exceptional papillomavirus-related diseases by BCG immunostimulation!. TRAITEMENT DES AFFECTIONS EXCEPTIONNELLES A PAPILLOMA VIRUS PAR IMMUNOSTIMULATION AU BCG." SEMAINE DES HOPITAUX, (1988) 64/22 (1525-1528). , XP002122559	1-10,24, 25
Y	the whole document	11-23
Y	COHEN HA ET AL: "Topical treatment of Kaposi's sarcoma, basal cell carcinoma and solar keratosis with ointment of BCG and cord factor" DERMATOLOGICA, vol. 158, no. 2, 1979, pages 117-25, XP002122560 the whole document	11-23
	— — — — — -/-	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

16 November 1999

Date of mailing of the international search report

03/12/1999

Name and mailing address of the ISA

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Authorized officer

Stein, A

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 99/02930

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	GB 2 179 858 A (BOEHRINGER INGELHEIM INT) 18 March 1987 (1987-03-18) page 1, line 28 - line 32 page 2, line 15 - line 34	13-22
X	STRAUSS M ET AL: "Aerodigestive tract papillomatosis: bacille Calmette-Guerin (BCG) immunotherapy." LARYNGOSCOPE, (1982 SEP) 92 (9 PT 1) 971-5. , XP002122562 page 971, column 2, line 10 -page 972, column 2, line 11 page 973, column 2, line 1 -page 974, column 1, line 53	24,25
X	MALISON M D ET AL: "Attempted BCG immunotherapy for condylomata acuminata 'letter!.' BRITISH JOURNAL OF VENEREAL DISEASES, (1981 APR) 57 (2) 148, 150. , XP002122563 the whole document	24,25
P,X	BOHLE A ET AL: "Treatment of recurrent penile condylomata acuminata with external application and intraurethral instillation of bacillus Calmette - Guerin." JOURNAL OF UROLOGY, (1998 AUG) 160 (2) 394-6. , XP002122564 the whole document	1-25

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 99/02930

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 2179858	A	18-03-1987	NONE